

REMARKS

**Unity of Invention**

Claims 1-26 are pending and are subject to a Unity of Invention restriction under 35 U.S.C. §§ 121 and 372 for reciting inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. (*See*, Office Communication, at page 2). Applicants respectfully traverse.

The Examiner has required election in the present application between:

Group I, claims 1-11 and 22, drawn to a HCV genotype 2a replicon, a cell comprising such, and a first method of use;

Group II, claims 12-15, 17, 23 and 24, drawn to a Hepatitis C virus and a cell comprising such, and a first method of making and using the virus;

Group III, claim 16, drawn to a method for screening for an anti-Hepatitis C virus substance comprising the use of a cell comprising the replicon particle or an HCV infected cell;

Group IV, claim 18, drawn to a method of producing an HCV vaccine comprising the use of a viral particle;

Group V, claims 19 and 20, drawn to a hepatotropic virus vector and a first method of making such;

Group VI, claim 21, drawn to a method for replicating or expressing a foreign gene in a cell comprising the use of the replicon of Group I;

Group VII, claim 25, drawn to methods for producing a virus vector comprising a foreign gene; and

Group VIII, claim 26, drawn to an antibody against an HCV 2a viral particle.

**For the purpose of examination of the present application, Applicants elect, with traverse, Group I, Claims 1-11 and 22.**

According to MPEP § 803, if the search and examination of an entire application can be made without a serious burden, the Examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions.

The Applicants respectfully disagree with the Examiner's interpretation of the unity of invention. According to MPEP § 1850, Determination of "Unity of Invention," with respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. Independent claims 1, 5, 22, 23 and 25 involve an interrelationship of replicon RNA which comprises nucleotide sequences and methods for producing cells that will replicate the hepatitis C RNA and eventually produce hepatitis C virus particles. Also according to MPEP § 1850, although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor maintained on the basis of a narrow, literal or academic approach. There should be a broad, practical consideration of the degree of interdependence of the alternatives presented.

Therefore, in light of the above arguments, there is unity of invention within the claims since it is based the above interrelationship of replicon RNA which comprises nucleotide sequences and methods for producing cells that will replicate the hepatitis C RNA and eventually

produce the virus particles. Because of this interrelationship within the claims, it would not be undue burden to search all of claims 1-26.

As such, Applicants respectfully request that the Examiner rejoins Groups I-VIII.

Reconsideration and withdrawal of the Unity of Invention Restriction Requirement of claims 1-26 are respectfully requested.

### **Elections**

The Examiner has required a further an election in the present application between:

(1) One of a selectable marker gene (claims 2 and 5), a reporter gene (claim 2), or both (claim 2); and

(2) One of the cells of claim 10.

**For the purpose of examination of the present application, Applicants elect (1) the selectable marker gene only and (2) the Huh7 cell, with traverse.**

**Claims 1-11 and 22 are directed to the elected species. As acknowledged by the Examiner on page 4 of the Unity of Invention Restriction Requirement, at least claims 1, 3, 4, 6-9, 11 and 22 are generic.**

The Applicant believes that claims 1-11 and 22 read upon the above elections.

In the event of rejoinder, Applicants understand that the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims must be fully examined for patentability according to the provisions of 37 C.F.R. § 1.104.

Reconsideration is respectfully requested.


**CONCLUSION**

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Paul D. Pyla, Registration No 59,228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: **OCT 16 2008**

Respectfully submitted,

By   
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